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**From:** Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]  
**Sent:** 4/14/2016 2:17:48 PM  
**To:** Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Kraft, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a94a4f199b247778abb02285a51b927-Kraft, Andrew]; Perovich, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e3c19d7f4db41bfa2477aa27ad83945-Perovich, Gina]  
**CC:** Glenn, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a2dc9210d2d4d02a623b33f87f49436-Glenn, Barbara]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]  
**Subject:** RE: Ramazzini study in FA

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**From:** Jones, Samantha  
**Sent:** Thursday, April 14, 2016 10:15 AM  
**To:** Kraft, Andrew <Kraft.Andrew@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>  
**Cc:** Glenn, Barbara <Glenn.Barbara@epa.gov>; Bussard, David <Bussard.David@epa.gov>  
**Subject:** RE: Ramazzini study in FA

**Deliberative Process / Ex. 5**

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**From:** Kraft, Andrew  
**Sent:** Thursday, April 14, 2016 8:20 AM  
**To:** Jones, Samantha <Jones.Samantha@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>  
**Cc:** Glenn, Barbara <Glenn.Barbara@epa.gov>; Bussard, David <Bussard.David@epa.gov>  
**Subject:** RE: Ramazzini study in FA

# Deliberative Process / Ex. 5

Thank you.

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**From:** Jones, Samantha  
**Sent:** Wednesday, April 13, 2016 5:49 PM  
**To:** Cogliano, Vincent <cogliano.vincent@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>  
**Cc:** Glenn, Barbara <Glenn.Barbara@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>  
**Subject:** RE: Ramazzini study in FA

# Deliberative Process / Ex. 5

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**From:** Cogliano, Vincent  
**Sent:** Monday, April 11, 2016 12:45 PM  
**To:** Perovich, Gina <Perovich.Gina@epa.gov>  
**Cc:** Jones, Samantha <Jones.Samantha@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>  
**Subject:** Re: Ramazzini study in FA

# Deliberative Process / Ex. 5

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Gina Perovich  
Deputy Director  
IRIS Program  
USEPA/ORD/NCEA  
703-347-8656

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**From:** Jones, Samantha  
**Sent:** Monday, April 11, 2016 12:12 PM  
**To:** Cogliano, Vincent <cogliano.vincent@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>  
**Cc:** Bussard, David <Bussard.David@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>  
**Subject:** RE: Ramazzini study in FA

I don't think that necessarily factored into the Agency's decision on RI. Can I get a little backstory or is this simply..."how do we incorporate (or not) RI data into IRIS assessments?"

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**From:** Cogliano, Vincent  
**Sent:** Monday, April 11, 2016 11:47 AM  
**To:** Perovich, Gina <Perovich.Gina@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>  
**Cc:** Bussard, David <Bussard.David@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>  
**Subject:** RE: Ramazzini study in FA

IARC's meeting was in 2004, the book was published in 2006.

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**From:** Perovich, Gina  
**Sent:** Monday, April 11, 2016 11:45 AM

**To:** Cogliano, Vincent <[cogliano.vincent@epa.gov](mailto:cogliano.vincent@epa.gov)>; Glenn, Barbara <[Glenn.Barbara@epa.gov](mailto:Glenn.Barbara@epa.gov)>  
**Cc:** Bussard, David <[Bussard.David@epa.gov](mailto:Bussard.David@epa.gov)>; Jones, Samantha <[Jones.Samantha@epa.gov](mailto:Jones.Samantha@epa.gov)>; Kraft, Andrew <[Kraft.Andrew@epa.gov](mailto:Kraft.Andrew@epa.gov)>  
**Subject:** RE: Ramazzini study in FA

What's the date on that volume?  
Was it considered already in NCEA's decision making process?  
The doc I copied from is what we (NCEA) released to the public.

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Gina Perovich  
Deputy Director  
IRIS Program  
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**From:** Cogliano, Vincent  
**Sent:** Monday, April 11, 2016 11:38 AM  
**To:** Perovich, Gina <[Perovich.Gina@epa.gov](mailto:Perovich.Gina@epa.gov)>; Glenn, Barbara <[Glenn.Barbara@epa.gov](mailto:Glenn.Barbara@epa.gov)>  
**Cc:** Bussard, David <[Bussard.David@epa.gov](mailto:Bussard.David@epa.gov)>; Jones, Samantha <[Jones.Samantha@epa.gov](mailto:Jones.Samantha@epa.gov)>; Kraft, Andrew <[Kraft.Andrew@epa.gov](mailto:Kraft.Andrew@epa.gov)>  
**Subject:** RE: Ramazzini study in FA

We can discuss this later (I'm pressed right now), but you might want to read the discussion in IARC volume 88, sections 3.2 and 5.3. In addition to the leukemias/lymphomas, testicular adenomas were increased, but in no other study. There were also large unexplained discrepancies between the two Soffritti publications.

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**From:** Perovich, Gina  
**Sent:** Monday, April 11, 2016 11:09 AM  
**To:** Glenn, Barbara <[Glenn.Barbara@epa.gov](mailto:Glenn.Barbara@epa.gov)>  
**Cc:** Bussard, David <[Bussard.David@epa.gov](mailto:Bussard.David@epa.gov)>; Cogliano, Vincent <[cogliano.vincent@epa.gov](mailto:cogliano.vincent@epa.gov)>; Jones, Samantha <[Jones.Samantha@epa.gov](mailto:Jones.Samantha@epa.gov)>; Kraft, Andrew <[Kraft.Andrew@epa.gov](mailto:Kraft.Andrew@epa.gov)>  
**Subject:** Ramazzini study in FA  
**Importance:** High

*Response to Barbara  
Input needed from Sam and Vince*

# Deliberative Process / Ex. 5

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## Update on Ramazzini Institute Data in IRIS Assessments – posted March 8, 2012

In June 2010, EPA decided to put four of its ongoing IRIS assessments on hold pending a review of some of the underlying studies used in the assessments. The four assessments included: Methanol, MTBE (methyl tert butyl ether), ETBE (ethyl tert butyl ether) and Acrylonitrile.

EPA made this decision after receiving a report from the National Toxicology Program (NTP) that reviewed results of some research studies completed by the Ramazzini Institute (RI), a lab in Italy that conducts animal testing to evaluate the potential cancer-causing effects of chemicals. The report found differences of opinion between NTP and RI scientists in the diagnosis of certain cancers reported in a study on methanol.

- To follow up on these findings, EPA collaborated with the National Institute of Environmental Health Sciences (NIEHS) to jointly sponsor an independent group of scientists, the Pathology Working Group (PWG), to review a larger group of animal studies performed in the RI lab.
- The report pointed out some instances where the presence of respiratory infections in RI study animals made definitive diagnoses difficult, and that some RI diagnoses, primarily certain leukemias and lymphomas, were not considered to be malignant tumors. As a result, PWG scientists found fewer numbers of leukemias and lymphomas than had been originally reported by the RI.
- Because of the differences of opinion between the RI and PWG scientists in diagnosing leukemias and lymphomas, EPA has decided not to rely on data from the RI on lymphomas and leukemias in these IRIS assessments. This decision will impact the IRIS assessments for methanol, MTBE and ETBE. The draft assessment for acrylonitrile was not affected, as EPA relied on data from sources other than RI to complete this IRI assessment.
- There was good agreement between the RI and PWG scientists in diagnosing solid tumors such as liver tumors from the RI study on vinyl chloride. EPA has therefore decided to continue to consider RI solid tumor data in IRIS assessments. RI solid tumor findings will be reviewed along with other data in determining the overall weight of evidence of carcinogenicity for substances on which EPA is conducting IRIS assessments.
- The PWG made recommendations for changes in RI's laboratory procedures and EPA hopes that RI will fully implement these recommendations to allow for the use of future RI data in IRIS assessments.

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Deputy Director, IRIS Program

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